

## **REMARKS**

Claims 7-9 are currently pending in the application. Only claim 7 is in independent form.

The Office Action dated July 12, 2004, states that the Oath or Declaration is defective and a new Oath or Declaration is attached hereto.

Claims 7-9 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Office Action dated July 12, 2004, has held that the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertain, or with which it is most nearly connected, to make and/or use the invention.

Specifically, the Office Action dated July 12, 2004, has held that the instant specification discloses that sera from both normal individuals and patients having ovarian cancer and phage display libraries expressing cDNAs of genes expressed in ovarian epithelial tumors and cell lines are used. The claimed method is then used for the identification of epitope-bearing phage clones displaying reactivity with antibodies in sera of patients with ovarian cancer but not in control sera. The claims have been amended to more specifically recite that differential biopanning occurs between a control sera or test sera and the patient's sera. This is done to selectively biopan for markers of disease. These markers are epitope bearing clones as recited in claim 7. This method is disclosed on page 25, lines 5-page 26-21. This portion of the specification provides details with regard to the biopanning experiments and how such experiments correlate to the epitope bearing clones that are identified. Additional support for the claims as currently amended is provided in the examples of the specification as filed.

The portion of the specification referred to above provides details with regard to how the markers are identified. More specifically, the markers are identified because they are present in the cancer patients versus healthy sera. The fact that these markers are present in the cancer patients indicates that such markers are indicative of the presence of cancer and as such are cancer markers that can be used in an array. The array is a pattern or grouping of markers that is

indicative of cancer. A single marker is not necessarily indicative of cancer. Many such markers are known to those of skill in the art and are however, the use of a single marker is not sufficient for use in detecting disease. Instead the presently claimed invention provides a method of creating an array of markers, or a combination of markers, that can be used to indicate the presence of cancer in patients. It is the combination of these markers that enables a more accurate analysis and identification of the presence of cancer in a patient. The attached abstracts indicate that p53 has been previously used as an indicator of breast cancer, however, the single marker is not sufficient for detecting cancer and instead there are large number of individuals who are not identified as having cancer. The combination or array of markers and method as recited in the presently pending claims provides for a more accurate analysis of the serum to determine the presence of cancer.

Further, the Office Action dated July 12, 2004, has questioned how markers can be determined by automatic analysis. As stated in the specification at page 30, lines 16 through the end of page 31, the determination of what epitopes are indicative of cancer can be automated. Such automation can occur by creating a program that analyzes the results of the differential biopanning and determines which epitopes reacted. Based on the above, and the amended claims it is respectfully submitted that the claims are supported by the specification as filed, and reconsideration of the rejection is respectfully requested.

Claim 7-9 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The Office Action dated July 12, 2004, states that claim 7 recites "selectively biopanning" and also appears to be missing steps. In order to further prosecution, claim 7 has been amended to recite "differentially biopanning," which is clearly defined in the specification as originally filed. Additionally, claim 7 has been amended to specifically recite all of the steps required for detecting a combination of markers for diagnosing the presence of a disease state or determining disease stage. Reconsideration of the rejection is respectfully

requested.


The Office Action dated July 12, 2004, states that claim 9 recited "earlier screens" but there is no indication that earlier screens have taken place. Claim 9 has been amended to recite that the classifier uses data from a template of data provided to the individual constructed into classifier. Support for this claim amendment is found throughout the specification as originally filed and specifically at p. 34, and reconsideration of the rejection is respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

The application is now in condition for allowance, which allowance is respectfully solicited.

Respectfully submitted,

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